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and it concluded in April 2012. Socioeconomic costs per patient were calculated. Costs were divided in 4 categories: direct health care costs (drugs, medical visits, exams, material), direct non-health care formal costs (professional carers, social services), direct non-health care informal costs (unpaid carers) and indirect costs (patient's and carer's productivity loss). Both patients and their carers completed a generic scale EQ-5D to measure HRQOL. **RESULTS:** A total of 697 patients and their carers responded the questionnaire, 28% affected by Cystic Fibrosis, 21% by Scleroderma and 11% by X-Fragile Syndrome. For most of the diseases an important part of the total costs were the direct non-health care informal costs, i.e. time of patient's main carer and other unpaid carers. Total annual cost per patient oscillated between 20.000 € (Haemophilia) and 200.000 € (Mucopolysaccharidosis). Regarding the HRQOL measured by EQ-5D, the most affected patients were those with Mucopolysaccharidosis and Duchenne Muscular Distrophy, which correlated with the HRQOL of their carers and total costs. **CONCLUSIONS:** Besides results on costs and HRQOL presented, the main outcome of BURQOL-RD is an integrated and harmonized set of instruments to assess and monitor socio-economic burden and HRQOL of patients affected by rare diseases and their carers. The tools developed by BURQOL-RD will also improve RD awareness and literacy among European citizens.

PSY46

IMPACT OF THE NEUROPATHIC PAIN COMPONENT ON QUALITY OF LIFE IN PATIENTS WITH LOW BACK PAIN

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OBJECTIVES: To explore the impact of neuropathic pain component on quality of life in patients with severe, chronic low back pain. **METHODS:** A phase 3b study was performed, including a total of 208 patients with severe, chronic low back pain who had been inadequately managed with World Health Organization Step I or II analgesics or had no regular analgesic treatment and were switched to tapentadol prolonged release. The likelihood of a neuropathic pain component (NPC) was determined using the painDETECT questionnaire: negative (score 0-12), unclear (score 13-18), or positive (score 19-38). The painDETECT questionnaire was previously shown to have high sensitivity, specificity and positive predictive accuracy. **RESULTS:** Mean pain intensity at baseline, measured with 11-point numerical rating scale, was slightly higher in patients with painDETECT positive score (7.6) than in patients with painDETECT unclear (7.3) and patients with painDETECT negative (7.1) score. However, patients with painDETECT positive score had the mean EQ-5D value substantially lower (0.31) than patients with pure nociceptive pain (0.44). Similarly, lower scores were detected in all dimensions of the SF-36 when NPC was present, especially in social functioning, role-physical, role-emotional, and mental health. Scores with the Hospital Anxiety and Depression Scale were worse for both dimensions if NPC was present. Whereas 12% of patients with pure nociceptive pain rated their overall quality of sleep as poor, there were 27% in patients with painDETECT positive subset. Moreover, in pre-study period, patients in the painDETECT positive subset consulted a doctor earlier and more frequently, visited more doctors because of their pain, changed more analgesic regimens since pain started, and were more absent from work than patients in the painDETECT negative subset. **CONCLUSIONS:** The presence of a neuropathic pain component appears to have a substantial detrimental impact on quality of life in patients with severe, chronic low back pain.

PSY47

THE RELATIONSHIP BETWEEN PAIN SEVERITY AND HEALTH UTILITIES: INFORMING CLINICAL TRIAL DESIGN TO SUBSTANTIATE VALUE

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OBJECTIVES: Achieving market access requires substantiating incremental value for the indicated patient population. The aim of this project was to provide an example of how mapping the relationship between clinical states and health utilities can inform early development strategy and clinical trial inclusion criteria. **METHODS:** US 2011 National Health and Wellness Survey data were used. Respondents with pain in the past month were included. General linear models were used to examine the relationship between pain level in the last week (0 to 10 scale) and health utilities (using the SF6D algorithm) while controlling for sociodemographics and health history. Models were replicated within pain subgroups (e.g., neuropathic pain, nocioceptive pain etc). **RESULTS:** A total of 24,778 respondents (33.04%) reported pain in the past month (mean age = 50.24; 51.71% were female). The range of health utilities was 0.35-1.00. Pain level was significantly associated with health utilities ($b=-0.025$, $p<.05$), though a cubic relationship was also identified whereby a 1-point reduction in pain was associated with a greater increase in utilities among those with mild pain (e.g., a reduction from 1 to 0 on the pain scale led to 0.027 increase in utilities) compared with those with severe pain (reduction from 10 to 9 lead to 0.010 increase in utilities). Subgroups were also investigated; for example, only a significant linear relationship (no higher order trends) between pain level and health utilities was observed among those with neuropathic pain ($b=-0.27$, $p<.05$). **CONCLUSIONS:** The overall relationship between the level of pain and health utilities was non-linear suggesting that more incremental value could be substantiated by reducing milder pain than more severe pain. However, not all subgroups followed this pattern emphasizing the benefits of understanding the relationship between estimated treatment effects and health utilities early in the developmental process to inform clinical trial design, optimize incremental value, and drive cost effectiveness.

PSY48

DEVELOPING A NATIONAL OUTCOMES TREATMENT REGISTRY FOR HEPATITIS C PATIENTS IN THE ERA OF THE DAAS

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OBJECTIVES: In January 2012, the protease inhibitors boceprevir and telaprevir were found to be cost effective in the Irish setting. The complexity of the treatment regimens, the high cost of the agents and the potential for increased patient morbidity prompted interested clinical specialist groups and health care service providers to collaborate in the establishment of an outcomes registry for Hepatitis C patients. The goal of the network was to optimise the quality of care of patients with hepatitis C (HCV) treated with directly acting antiviral therapy (DAA). The aim is to describe the process of development of a national outcomes treatment registry under the auspices of the Irish Hepatitis C Outcomes Registry Network (ICORN). **METHODS:** The review took into account the challenges and considerations for the design, development and implementation of the registry. Identified issues in the development phase included governance, stakeholder involvement, feasibility, funding, analysis and ethics and privacy. Those identified in the design phase included the study design, outcomes and research questions. The implementation phase will involve training and education, data capture, database management, monitoring, reporting systems and research. **RESULTS:** The Executive Committee was established in the first instance, with the subsequent appointment of a clinical advisory group sub-committee to develop clinical guidelines and treatment protocols. The outcomes required of the registry were ratified. Seven centres of excellence were identified for data collection. A data capture tool was designed in collaboration with software expertise. Data protection considerations were put in place. A clear reporting structure for funding for the registry was established. **CONCLUSIONS:** Observational data generated through the registry allows real time monitoring of safety, effectiveness and cost effectiveness of triple therapy regimes in HCV. This project is a reference case in Ireland for extension of health technology assessment beyond the reimbursement decision.

PSY49

TREATMENT PATTERNS IN PSORIATIC ARTHRITIS (PSA) PATIENTS NEWLY INITIATED ON NON-BIOLOGIC DISEASE MODIFYING ANTI-RHEUMATIC DRUGS (DMARDS)

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OBJECTIVES: To describe treatment changes following the initiation of a non-biologic DMARD in PsA patients. **METHODS:** Adult patients with ≥ 2 PsA diagnoses (from office visits) with continuous insurance coverage ≥ 6-month before and ≥ 12-month post-index date (i.e., first prescription of a non-biologic DMARD) were selected from the MarketScan Commercial Claims database (2005-2009). Patients who used a biologic/non-biologic DMARDs or had a diagnosis of ankylosing spondylitis before the index date were excluded. Treatment discontinuation was defined as a treatment interruption ≥ 60 consecutive days. Therapy modification was defined as a switch (initiation of a biologic/non-biologic DMARD [not used at the index date] within 60 days of the index biologic discontinuation date) or a therapy augmentation (use of a non-biologic/biologic DMARD [not used at the index date] concomitantly with the index non-biologic DMARD for ≥ 28 consecutive days). The 12-month therapy modification, switch, and augmentation rates were reported. **RESULTS:** A total of 1,698 PsA patients met the selection criteria; 71.7% initiated on methotrexate, 17.5% on sulfasalazine. Over the 12-month study period, 72.5% of the patients had ≥1 therapy change (median time: 86 days). More specifically, 57.7% of patients discontinued the index non-biologic DMARD, 13.1% switched to a biologic DMARD, 9.3% switched to another non-biologic DMARD, 21.4% had a therapy augmentation with a biologic DMARD and 7.4% had a therapy augmentation with another non-biologic DMARD. Among patients who initiated a biologic during the study period (N=513), 90.8% did not use other oral DMARDs, while 9.2% also initiated a second oral DMARD either in combination or sequentially. **CONCLUSIONS:** This study suggests that PsA patients newly initiated on a non-biologic DMARD do not remain on the index therapy for a long period of time. Most patients switched to or added on biologics quickly without using a second oral DMARD.

RESEARCH POSTER PRESENTATIONS – SESSION V
SELECTED HEALTH CARE TREATMENT STUDIES

HEALTH SERVICES - Clinical Outcomes Studies

PHS1

THE EFFECT OF POSITIONING AND PNF-EXERCISE TO POSTOPERATIVE BLEEDING AFTER HIP REPLACEMENT

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OBJECTIVES: Postoperative positioning has beneficial effects on postoperative blood-saving, HGB and HTC reduction after knee replacement, and reduces the complications of transfusion. **METHODS:** Total of 96 people with hip replacement (age 69±20) were included in 4 groups who were treated on Orthopaedic Department in Zala County Hospital in 2012. *I.a.group:* traditional way of physiotherapy following the hospital protocol (not upraised lower limb) *I.b.group:* the same to I.a., supplemented with one special exercise from PNF-method (irradiation, effecting the operated side; repeat it 5-15 times/hour during the first 3 day) *II.a.group:* placed the lower limb in 30° hip and knee flexion + traditional physiotherapy, *II.b.group:* same to II.a, supplemented with the special PNF exercise. The postoperative blood volume (after 6, 24, 48, 72 hours) and HGB, HTC (pre- and postop.24[h]) were measured. Data were analysed by Wilcoxon-tests applying SPSS statistic software. **RESULTS:** The 30°hip and knee flexion increased the postoperative bleeding